



**For Previously Untreated Adults with  
Advanced or Metastatic Esophageal  
Squamous Cell Cancer (ESCC)**

**A CHANCE TO LIVE LONGER™**

Actor portrayals

OPDIVO will not work for everyone. Individual results may vary.  
Please see information about the clinical trials on pages 3-5. Please see serious side effects on the right panel.

## What is OPDIVO?

OPDIVO is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum to treat adults who have **cancer of the tube that connects the throat to the stomach (esophageal cancer)** and their cancer:

- ✓ Is a type called squamous cell carcinoma, **AND**
- ✓ Cannot be removed with surgery (advanced), or
- ✓ Has spread to other parts of the body (metastatic) **and** you have not already had treatment for your advanced or metastatic esophageal cancer.

It is not known if OPDIVO is safe and effective in children younger than 18 years of age.

Information provided in this brochure is not a substitute for talking with your healthcare professional.  
Your healthcare professional is the best source of information about your disease.

**i** Please see **Important Facts on pages 9-10 and U.S. Full Prescribing Information and Medication Guide for OPDIVO.**

**OPDIVO**<sup>®</sup>  
(nivolumab)

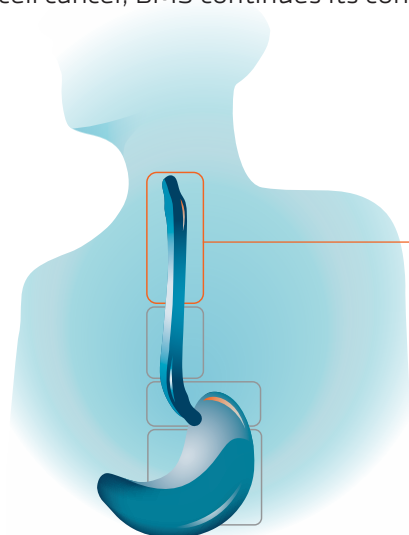
INJECTION FOR INTRAVENOUS USE 10 mg/mL

# OPDIVO with chemotherapy\* is FDA-approved as a first treatment option for adults with advanced or metastatic esophageal squamous cell carcinoma



Bristol Myers Squibb has been at the forefront in developing immunotherapy-based treatments for upper gastrointestinal (UGI) cancers. Our ongoing research has helped to further the fight against these challenging conditions.

With the FDA approval of OPDIVO immunotherapy plus chemotherapy for advanced or metastatic **esophageal squamous** cell cancer, BMS continues its commitment to helping patients.



■ **esophageal squamous cell carcinoma (esophagus)**

## Select Important Safety Information

OPDIVO is a medicine that may treat certain cancers by working with your immune system. OPDIVO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. Some of these problems may happen more often when OPDIVO is used in combination with another therapy.

\*Chemotherapy containing a fluoropyrimidine and platinum.

### What are the serious side effects of OPDIVO® (nivolumab)?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

#### Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

- lung problems
- kidney problems
- complications of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)
- intestinal problems
- skin problems
- severe infusion reactions
- liver problems
- hormone gland problems

### What are the most common side effects?

The most common side effects of OPDIVO when used alone include:

- feeling tired
- cough
- upper respiratory tract infection
- rash
- vomiting
- fever
- pain in muscles, bones, and joints
- shortness of breath
- headache
- itchy skin
- constipation
- stomach-area (abdominal) pain
- diarrhea
- decreased appetite
- urinary tract infection
- nausea
- back pain

The most common side effects of OPDIVO when used in combination with fluoropyrimidine and platinum-containing chemotherapy include:

- nausea
- decreased appetite
- vomiting
- numbness, pain, tingling, or burning in your hands or feet
- feeling tired
- stomach area (abdominal) pain
- constipation
- mouth sores
- pain in muscles, bones, and joints
- diarrhea

These are not all the possible side effects. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.



Please see additional Important Facts on pages 9–10 and U.S. Full Prescribing Information and Medication Guide for OPDIVO.

# OPDIVO + chemotherapy\* may be right for you



OPDIVO + chemotherapy\* is FDA-approved for previously untreated adults with advanced or metastatic **esophageal squamous** cell cancer, regardless of PD-L1<sup>†</sup> biomarker status



## WHAT'S A BIOMARKER?

A **PD-L1 biomarker** is a molecule found in the body in tissues, blood, or fluid. Biomarkers may show if there is a disease or condition present. Your doctor may test you to see if you have the PD-L1 biomarker.

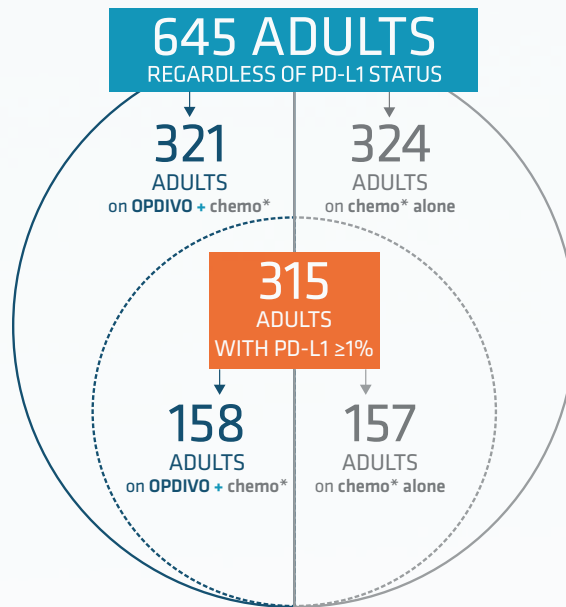
### A LOOK AT THE OPDIVO + CHEMOTHERAPY\* STUDY

Part of a larger clinical trial, the study included 645 patients, regardless of their PD-L1 biomarker status.

All had **previously untreated** advanced or metastatic **esophageal squamous** cell cancer.

Of these, 315 adults had **PD-L1 ≥1%**.

\*\*Fluorouracil and cisplatin.



## Ask your doctor about OPDIVO + chemotherapy

\*Chemotherapy containing a fluoropyrimidine and platinum.

†Programmed death-ligand 1.

### What are the serious side effects of OPDIVO® (nivolumab)?

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- headache
- itchy skin
- constipation
- stomach-area (abdominal) pain
- diarrhea
- decreased appetite
- urinary tract infection
- nausea
- back pain
- weakness

The most common side effects of OPDIVO when used in combination with fluoropyrimidine and platinum-containing chemotherapy include:

- nausea
- decreased appetite
- vomiting
- numbness, pain, tingling, or burning in your hands or feet
- feeling tired
- constipation
- stomach area (abdominal) pain
- mouth sores
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# More people were alive on OPDIVO + chemotherapy\* compared to chemotherapy\* alone



In a study of 645 adults with previously untreated advanced or metastatic **esophageal squamous** cell cancer, 321 received OPDIVO in combination with chemotherapy\* and 324 received chemotherapy\* alone. Of these, 315 adults had PD-L1  $\geq 1\%$ . In this group, 158 adults received OPDIVO in combination with chemotherapy\* while 157 adults received chemotherapy\* alone.

## Adults with PD-L1 $\geq 1\%$ (n=315)

PEOPLE ALIVE AT 1 YEAR



OPDIVO + chemotherapy\* proven to **lower** the risk of dying by **46%** compared to chemotherapy\* alone

Half of the adults who were on **OPDIVO + chemotherapy\*** were alive at 15.4 months compared to half being alive on chemotherapy\* alone at 9.1 months.

## All adults regardless of PD-L1 status (n=645)

PEOPLE ALIVE AT 1 YEAR



OPDIVO + chemotherapy\* proven to **lower** the risk of dying by **26%** compared to chemotherapy\* alone

Half of the adults who were on **OPDIVO + chemotherapy\*** were alive at 13.2 months compared to half being alive on chemotherapy\* alone at 10.7 months.

## Adults with PD-L1 $\geq 1\%$

For adults with a PD-L1 biomarker  $\geq 1\%$ , half of the adults on **OPDIVO + chemotherapy\*** went 6.9 months without their cancer spreading, growing, or getting worse compared to half who went 4.4 months without their cancer spreading, growing, or getting worse on **chemotherapy\* alone**.

**OPDIVO + chemotherapy\*** reduced the risk of cancer spreading, growing, or getting worse by 35% compared to **chemotherapy\* alone**.

\*Fluorouracil and cisplatin.

**OPDIVO will not work for everyone. Individual results may vary.**

### What are the serious side effects of OPDIVO® (nivolumab)?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

#### Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

- lung problems
- kidney problems
- complications of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)
- intestinal problems
- skin problems
- severe infusion reactions
- liver problems
- hormone gland problems

### What are the most common side effects?

The most common side effects of OPDIVO when used alone include:

- feeling tired
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- vomiting
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- pain in muscles, bones, and joints
- shortness of breath
- headache
- itchy skin
- constipation
- stomach-area (abdominal) pain
- diarrhea
- decreased appetite
- urinary tract infection
- nausea
- back pain
- weakness

The most common side effects of OPDIVO when used in combination with fluoropyrimidine and platinum-containing chemotherapy include:

- nausea
- decreased appetite
- vomiting
- numbness, pain, tingling, or burning in your hands or feet
- feeling tired
- constipation
- stomach area (abdominal) pain
- mouth sores
- diarrhea
- pain in muscles, bones, and joints

These are not all the possible side effects. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

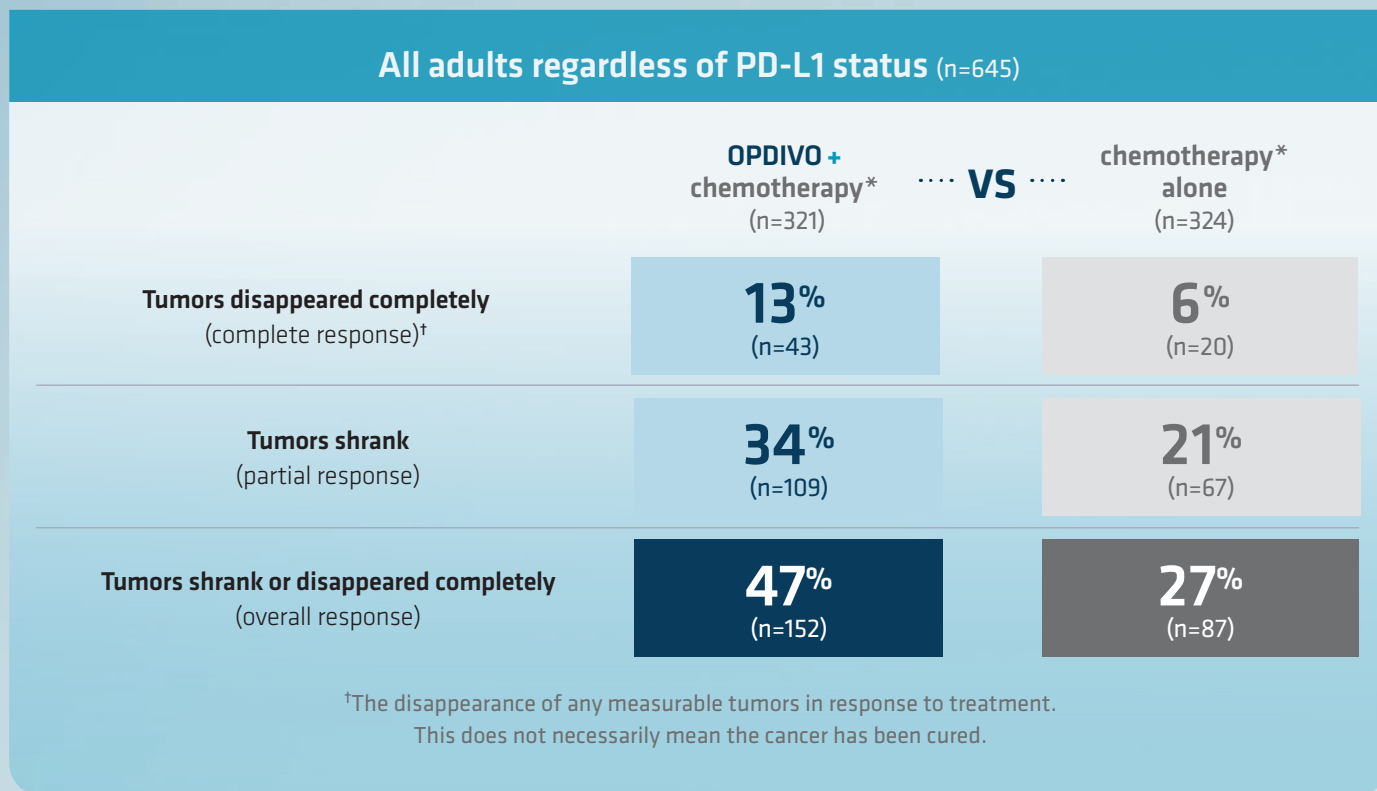


Please see additional Important Facts on pages 9–10 and U.S. Full Prescribing Information and Medication Guide for OPDIVO.

# More people had their tumors shrink or disappear on OPDIVO + chemotherapy\* regardless of PD-L1 status



In a study of 645 adults with previously untreated advanced or metastatic **esophageal squamous** cell cancer, 321 received OPDIVO in combination with chemotherapy\* and 324 received chemotherapy\* alone. More of the OPDIVO + chemotherapy\* adults had their tumors shrink or disappear compared to the adults on chemotherapy\* alone.



\*Fluorouracil and cisplatin.

**OPDIVO will not work for everyone. Individual results may vary.**

## What are the serious side effects of OPDIVO® (nivolumab)?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

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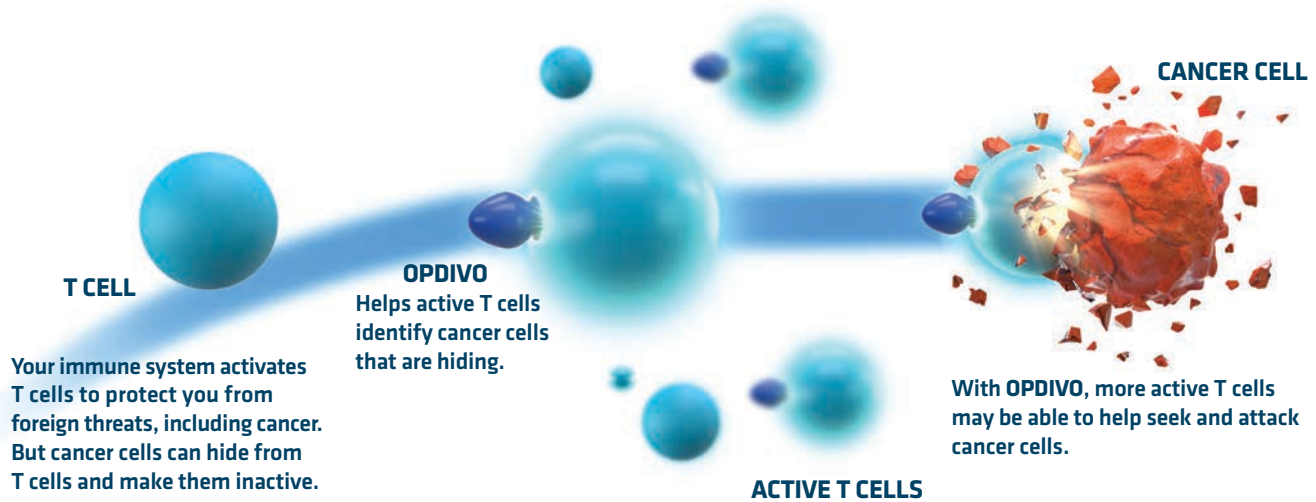
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**Please see additional Important Facts on pages 9–10 and U.S. Full Prescribing Information and Medication Guide for OPDIVO.**

## OPDIVO Helps Seek and Attack: How it works with your immune system



OPDIVO can cause your T cells to attack healthy cells contained within organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death, and may happen anytime during treatment or even after treatment has ended. You may have more than one of these problems at the same time. Your doctor will check you for these problems during treatment. Your doctor may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment if you have severe side effects. Please see pages [9–10](#) for a list of possible side effects and what to look out for.

### What are the serious side effects of OPDIVO® (nivolumab)?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

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Please see additional Important Facts on pages [9–10](#) and [U.S. Full Prescribing Information and Medication Guide for OPDIVO](#).

# Work with your doctor to choose the treatment schedule that's right for you

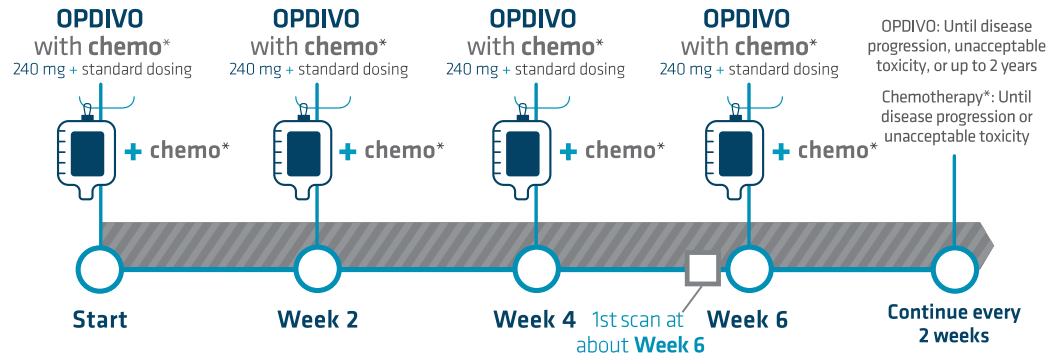


## OPDIVO 240 MG every 2 weeks

### WITH chemotherapy\*

OPDIVO is delivered into your vein through an intravenous (IV) line. You may be given **OPDIVO + chemotherapy\*** on the same day every 2 weeks.

Infusion time 30 minutes **OPDIVO**

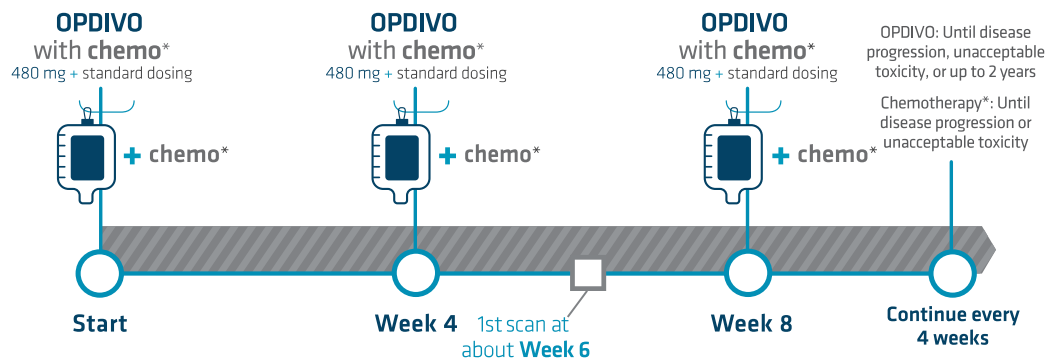


## OPDIVO 480 MG every 4 weeks

### WITH chemotherapy\*

OPDIVO is delivered into your vein through an intravenous (IV) line. You may be given **OPDIVO + chemotherapy\*** on the same day every 4 weeks.

Infusion time 30 minutes **OPDIVO**



\*Your doctor will prescribe you a type of chemotherapy that contains fluoropyrimidine and platinum.

### What are the serious side effects of OPDIVO® (nivolumab)?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

#### Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

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The most common side effects of OPDIVO when used in combination with fluoropyrimidine and platinum-containing chemotherapy include:


- nausea
- decreased appetite
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Please see additional Important Facts on pages 9–10 and U.S. Full Prescribing Information and Medication Guide for OPDIVO.




 OPDIVO is given through intravenous (IV) infusion. The medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional—usually in the arm or hand. Chemotherapy may be given on the same day.

 **Talk to your doctor about which treatment schedule may be right for you.** These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointments to let them know how you're feeling and ask any questions you may have.

**See pages 9–10 for information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment.**

 **If you miss an appointment,** call a healthcare provider right away. Try to schedule your appointments for the same day of the week and the same time of day to make them easier to remember. It is important for you to keep all appointments with your healthcare provider.

 Visit [www.OPDIVO.com](http://www.OPDIVO.com) for more information.

### What are the serious side effects of OPDIVO® (nivolumab)?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

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# Important Facts About OPDIVO® (nivolumab)

This is a summary of important information that you need to know about OPDIVO. Your healthcare team can work with you to help answer any questions you may have about OPDIVO. Keep this information in a safe place so you can refer to it before and during your treatment.

**Look out for the following icons as you read:**

 Talk to your healthcare team

 Call a healthcare provider right away

 Helpful information to remember

## What is OPDIVO?


OPDIVO is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum to treat adults who have **cancer of the tube that connects the throat to the stomach (esophageal cancer)** and their cancer:

- ✓ Is a type called squamous cell carcinoma, **AND**
- ✓ Cannot be removed with surgery (advanced), or
- ✓ Has spread to other parts of the body (metastatic) **and** you have not already had treatment for your advanced or metastatic esophageal cancer.

It is not known if OPDIVO is safe and effective in children younger than 18 years of age.

## What is the most important information I should know about OPDIVO?

OPDIVO is a medicine that may treat certain cancers by working with your immune system. OPDIVO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. Some of these problems may happen more often when OPDIVO is used in combination with another therapy.

 **Get medical help immediately** if you develop any of these signs or symptoms or they get worse. It may keep these problems from becoming more serious. Your healthcare team will check you for these problems during treatment and may treat you with corticosteroid or hormone replacement medicines. If you have severe side effects, your healthcare team may also need to delay or completely stop your treatment.

### What are the serious side effects of OPDIVO?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

**Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:**

**Lung problems** – Things to look out for may include:

- new or worsening cough
- shortness of breath
- chest pain

**Intestinal problems** – Things to look out for may include:

- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdominal) pain or tenderness

**Liver problems** – Things to look out for may include:

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

**Hormone gland problems** – Things to look out for may include:

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

**Kidney problems** – Things to look out for may include:

- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite

**Skin problems** – Things to look out for may include:

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in the mouth or nose, throat, or genital area

**Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune system problems that can happen with OPDIVO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:**

- Chest pain, irregular heartbeat, shortness of breath, swelling of ankles
- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising


## What are the possible side effects of OPDIVO?

**OPDIVO can cause serious side effects, including:**

See the previous section, **“What is the most important information I should know about OPDIVO?”**

**Severe infusion reactions** – Things to look out for may include:

- chills or shaking
- shortness of breath
- feel like passing out
- itching or rash
- or wheezing
- fever
- flushing
- dizziness
- back or neck pain

 **Tell your healthcare team** right away if you get these symptoms during an infusion of OPDIVO.

**Complications of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO. Your healthcare provider will monitor you for these complications.

## What are the most common side effects of OPDIVO?

The most common side effects of OPDIVO when used alone include:


- **feeling tired**
- **cough**
- **upper respiratory tract infection**
- **rash**
- **vomiting**
- **fever**
- **pain in muscles, bones, and joints**
- **shortness of breath**
- **headache**
- **itchy skin**
- **constipation**
- **stomach-area (abdominal) pain**
- **diarrhea**
- **decreased appetite**
- **urinary tract infection**
- **nausea**
- **back pain**
- **weakness**

The most common side effects of OPDIVO when used in combination with fluoropyrimidine and platinum-containing chemotherapy include:

- **nausea**
- **feeling tired**
- **stomach area (abdominal) pain**
- **numbness, pain, tingling, or burning in your hands or feet**
- **constipation**
- **pain in muscles, bones, and joints**
- **decreased appetite**
- **mouth sores**
- **diarrhea**
- **vomiting**

These are not all the possible side effects. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

## What should I discuss with my healthcare team before receiving OPDIVO?

 **Tell your healthcare provider about all your medical conditions, including if you:**


- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area in the past and have received other medicines that are like OPDIVO
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. OPDIVO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO passes into your breast milk. Do not breastfeed during treatment with OPDIVO and for 5 months after the last dose of OPDIVO.



### **Females who are able to become pregnant:**

Your healthcare provider should do a pregnancy test before you start receiving OPDIVO.

- You should use an effective method of birth control during your treatment and for at least 5 months after the last dose of OPDIVO. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO.

 **Tell your healthcare provider about all the medicines you take, including:**

- prescription medicines
- vitamins
- over-the-counter medicines
- herbal supplements

 **For more information, please see [U.S. Full Prescribing Information and Medication Guide for OPDIVO](#), or talk to your healthcare team.**

# Financial Resources

## Patient Access, Reimbursement, and Co-Pay Support

Available through  
**Bristol Myers Squibb Access Support®**

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That's why we offer the BMS Access Support program, which provides resources to help patients understand their insurance coverage and find information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

For more information, ask your doctor, visit **BMS Access Support**, or call BMS Access Support at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday.



Please see additional Important Facts on pages 9–10 and U.S. Full Prescribing Information and Medication Guide for OPDIVO.

# Connect With Others

Here are some support groups you can reach out to during your treatment journey\*



**Debbie's Dream Foundation: Curing Stomach Cancer** | [debbiesdream.org](http://debbiesdream.org)  
Debbie's Dream Foundation: Curing Stomach Cancer is a 501(c)(3) non-profit organization dedicated to raising awareness about stomach cancer, advancing funding for research, and providing education and support internationally to patients, families, and caregivers.



**Esophageal Cancer Action Network (ECAN)** | [ECAN.org](http://ECAN.org)  
ECAN is dedicated to saving lives by sounding the alarm about the link between reflux disease and cancer, promoting early detection, advocating for funding and progress in medical research, and educating patients and caregivers within a supportive, compassionate community.



**EC Aware** | [ec-aware.org](http://ec-aware.org)  
The mission of EC Aware (formerly ECAA) is to promote awareness of the disease for prevention and to foster community that together can provide support and information to those in need.



**Gastric Cancer Foundation** | [gastriccancer.org](http://gastriccancer.org)  
Today, Gastric Cancer Foundation provides hope and support for thousands of patients across the United States and around the world. Our mission is straightforward: to find a cure for gastric cancer.



**GI Cancers Alliance** | [gicancersalliance.org](http://gicancersalliance.org)  
The GI Cancers Alliance works to raise awareness, provide education and advocate to prevent, treat and cure gastrointestinal cancers through a collaboration between advocacy groups, industry and institutional partners.



**Raymond Foundation** | [theraymondfoundation.org](http://theraymondfoundation.org)  
We formed The Raymond Foundation to honor Margaret and Patrick Raymond who both passed away from this horrific disease while in the prime of their lives. We do not want one more family to be affected by this disease. To that end, we are tireless advocates for colon cancer education, outreach and patient empowerment.

*\*Bristol Myers Squibb does not endorse these organizations. The information and links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician's medical advice.*

To learn more about additional resources, please visit [www.OPDIVO.com](http://www.OPDIVO.com).

## SIGN UP for OPDIVO with You.

OPDIVO with You means just that: we're here to help you better understand OPDIVO, whether you or a loved one are just considering OPDIVO or already have an OPDIVO prescription. This complimentary program includes the following resources. Sign up and you'll receive:



### Helpful Information

Get useful tips, tools, and educational materials that can help you learn more about OPDIVO and may help support your care.



### Support and Advocacy Groups

We can direct you to organizations that may be helpful for the challenges you may face.



### A Care Counselor as Close as Your Phone

If you are prescribed OPDIVO and sign up for this additional resource, you'll be able to speak with a registered nurse. A Care Counselor can answer questions about treatment and help you to be a more informed partner with your doctor. Care Counselors cannot provide medical advice. **Your healthcare professional is the best source of information about your health.**

**If you'd like to sign up for the OPDIVO with You program, or if you have general questions about OPDIVO, call 1-855-OPDIVO-1 (1-855-673-4861) 8 AM to 8 PM ET, Monday to Friday, or visit [www.OPDIVOwithYou.com](http://www.OPDIVOwithYou.com)**



For more information,  
call **1-855-OPDIVO-1** or visit  
**[www.OPDIVO.com](http://www.OPDIVO.com)**



### SHARE TO INSPIRE

Because your story can help inspire another.

Call us toll-free at **1-855-436-5866**



Please see **Important Facts on pages 9-10** and **U.S. Full Prescribing Information and Medication Guide** for OPDIVO.



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